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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,997	03/24/2004	Wenfeng Xu	04-04	4594

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EXAMINER	
SKELDING, ZACHARY S	

ART UNIT	PAPER NUMBER
1644	

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07/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/807,997	XU ET AL.	
	Examiner	Art Unit	
	Zachary Skelding	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2007 and 18 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,10-28 and 35-40* is/are pending in the application.

4a) Of the above claim(s) *1-5,15-28 and 35-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-14 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *7-18-07*.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. It is noted that a Final Office Action was mailed June 25, 2007 in response to applicant's amendment to the specification and claims, filed April 11, 2007. However the Office Action mailed June 25, 2007 was the same as the first Office Action on the merits for this application which was sent December 11, 2006.

   Thus, the Office Action mailed June 25, 2007 was sent in error and is hereby withdrawn.

   Accordingly, the instant Office Action is being sent which is responsive to applicant's amendment and Remarks filed April 11, 2007.

   Applicant's deadline for response is hereby reset based on the mailing date of the instant Office Action.

   The examiner apologizes to applicant for any inconvenience in this matter. Furthermore, the examiner thanks applicant for bringing this matter to the examiner's attention in the phone call of July 18, 2007.

2. Applicant's amendment to the specification and claims, filed April 11, 2007 has been entered.

   Claims 6-9 and 29-34 have been canceled.

   Claims 10-14 have been amended.

   Claim 40 has been added.

   Claims 1-5, 10-28 and 35-40 are pending.

3. It is noted that applicant has canceled all the previously pending claims that recited the elected species of antibody against a particular epitope of SEQ ID NO: 8, i.e., an "antibody that binds a polypeptide consisting of amino acid residues 42-102 of SEQ ID NO:8."

   Given that the remaining claims that read on the elected invention recite antibody to full-length SEQ ID NO: 8. Accordingly, applicant's election of species of September 20, 2006 has been rendered moot.

   Thus, claims 10-14 and 40 are under consideration as they read on antibodies to SEQ ID NO: 8 that reduces the proinflammatory activity of SEQ ID NO: 8 in various diseases.

   Accordingly, claims 1-5, 15-28 and 35-39 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being directed to a non-elected invention.

4. The previous objection to the specification has been withdrawn in view of applicant's amendment to the specification.

   The previous rejection under 35 U.S.C. § 112, 2nd paragraph has been withdrawn in view of applicant's amendment to the claims.

   The previous rejection under 35 U.S.C. § 112, 1st paragraph has been withdrawn in view of applicant's amendment to the claims.

   The previous rejection of claims 6-9 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of apparently commonly assigned US Patent No. 7,119,175 in view of...is withdrawn in view of applicant's amendment to the claims.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

   > A person shall be entitled to a patent unless –
   >
   > (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 10-12 are rejected under 35 U.S.C. § 102(b)** as anticipated by Thompson et al. (USPN 2002/0042366-A1, cited on applicant's IDS of August 5, 2005)

   This is a new Grounds of Rejection necessitated by applicant's amendment to the claims.

   Thompson teaches a humanized antibody or antibody thereof that binds a polypeptide comprising SEQ ID NO: 8 (IL-20) and reduces its proinflammatory activity in psoriasis, arthritis and inflammatory bowel disease. (see entire document, for example, Abstract, page 1, paragraph [0007], paragraph [0046] bridging pages 4-5 and Example 6).

   Moreover, it should be noted that an anti-SEQ ID NO: 8 antibody that reduces the proinflammatory activity of SEQ ID NO: 8 should reduce the proinflammatory activity of SEQ ID NO: 8 in any disease involving SEQ ID NO: 8 inflammation, including, for example, multiple sclerosis as well as psoriasis.

   Thus, Thompson anticipates the instant claims.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

   > (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. **Claims 10-14 and 40 are rejected under 35 U.S.C. 103(a)** as being unpatentable over Thompson et al. (USPN 2002/0042366-A1), in view of Xu et al. (WO 2003/083062, of record), Koumenis et al. (Int J Pharm. 2000 Mar 30;198(1):83-95, of record) and Reff et al. (Crit Rev Oncol Hematol. 2001 Oct;40(1):25-35, of record)(See entire documents).

This is a new Grounds of Rejection necessitated by applicant's amendment to the claims.

In addition to the teachings of Thompson given in section 5 above, Thompson further teaches that cells expressing the IL-20 receptor are activated by IL-20 to secrete proinflammatory cytokines (see entire document, in particular Example 4).

The claimed invention differs from the reference teaching in the recitation of "wherein the antibody further comprises "a radionuclide, enzyme, substrate, cofactor, fluorescent marker, chemiluminescent marker, peptide tag, magnetic particle, drug, or toxin" and "wherein the antibody further comprises PEGylation" and wherein the antibody is a "human" antibody.

Xu teaches an IL-20 related cytokine known as "IL-TIF". Xu also teaches that IL-20 and IL-TIF share a receptor subunit, that IL-20 and IL-TIF activity are implicated in the pathogenesis of psoriasis, and that mice transgenic for IL-20 and IL-TIF have similar phenotypes (see, in particular, page 65, 1st paragraph to page 67, 1st paragraph). Finally, Xu teaches anti-IL-TIF antibodies can be labeled with a radionuclide, enzyme, substrate, cofactor, fluorescent marker, chemiluminescent marker, peptide tag, magnetic particle, drug, or toxin or pegylated (see entire document, in particular, paragraph bridging pages 5-6 to paragraph bridging page 10, 3rd paragraph; page 53, 1st paragraph; page 55, 1st paragraph to page 57, 1st paragraph; page 87, 1st paragraph to page 89, 2nd paragraph, and claims 3 and 5, for example).

Reff teaches linking toxins and drugs to antibodies (see entire document, in particular page 28, section 3.2-3.3). Reff further teaches human and humanized antibodies.

Koumenis teaches the PEGylation of an anti-interleukin antibody, anti-IL-8, to increase serum half-life and to reduce immunogenicity (see entire document, in particular Introduction, page 84).

Given the teaching of Thompson and Xu, it would have been obvious to one of ordinary skill in the art, and one of ordinary skill in the art would have been motivated to label the anti-IL-20 antibodies of Thompson using the radionuclide, enzyme, substrate, cofactor, fluorescent marker, chemiluminescent marker, peptide tag or magnetic particle labels recited by Xu because, as taught by both Thompson and Xu, IL-20 and IL-TIF activity are implicated in the pathogenesis of psoriasis, and thus one of ordinary skill in the art would have been motivated to prepare an antibody to detect the expression of IL-20 in psoriatic skin by labeling the antibody according to Thompson with the labels of Xu. Also, it would have been further obvious to one of ordinary skill in the art to label anti-IL-20 antibodies as claimed for a variety of other uses long known to one of ordinary skill in the art as of applicant's date of invention, such as such as cell sorting, immunohistology and immunoassays given the role of IL-20 in various diseases.

Moreover, as taught by Xu, Koumenis and Reff, one of ordinary skill in the art would have been motivated to prepare human or pegylated versions of the anti-IL-20 antibodies of Thompson because such antibodies have lower immunogenicity and a longer serum half-life than alternative molecules like mouse/human chimeric antibodies. As is well known to one of ordinary skill in the art, antibodies are generally administered by injection in a physicians office, and thus patients and their physicians greatly desire antibodies with a long serum half-life and low immunogenicity.

Furthermore, given the teaching of Thompson that antagonist of SEQ ID NO: 8 can be used to treat a variety of diseases encompassed by the instant claims by blocking the pro-inflammatory effects of IL-20 on cells that mediate said diseases, one of ordinary skill in the art would have been motivated to prepare an anti-IL-20 antibody toxin or drug conjugate as taught by Xu and Reff to deliver a toxin or drug to a cell that expresses the IL-20 receptor thereby killing the inflammatory cells and treating said diseases.

Given the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in arriving at the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Thus, the instant claims are unpatentable over Thompson in view of Xu, Reff and Koumenis.

9. **Claims 10-14 and 40 are <u>provisionally</u> rejected** on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 8, 10, 12, 14, 17-23, 25 and 26 of copending and apparently commonly assigned USSN 10/789,968, in view of Xu et al. (WO 2003/083062), Koumenis et al. (Int J Pharm. 2000 Mar 30;198(1):83-95), and Reff et al. (Crit Rev Oncol Hematol. 2001 Oct;40(1):25-35)(See entire documents).

This is a New Grounds of Rejection necessitated by applicant's amendment to the claims.

The claims of **USSN 10/789,968** recite an antibodies that bind SEQ ID NO: 2 and various SEQ ID NO: 2 peptides, wherein SEQ ID NO: 2 is the same as SEQ ID NO: 8 of the instant application.

The claims currently under consideration which are not anticipated by **USSN 10/789,968** differ from the claims of **USSN 10/789,968** in the recitation of "wherein the antibody or antibody fragment reduces the pro-inflammatory activity of IL-20... in a disease selected from the group consisting of psoriasis..." and wherein the antibody further comprises certain labels or pegylation.

However, for the reasons stated in section 9 above, it would have been obvious to one of ordinary skill in the art, and one of ordinary skill in the art would have been motivated and had a reasonable expectation of success of combining the claims of USSN 10/789,968 with teachings of Xu et al., Koumenis et al. and Reff et al. to arrive at the instant claims.

This is a provisional obviousness-type double patenting rejection.

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PHILLIP GAMBEL, PH.D JD
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TC 1600
7/18/07

Zachary Skelding, Ph.D.
Patent Examiner
July 18, 2007